

Attorney Docket No.: J3692(C)
Serial No.: 10/531,155
Filed: September 26, 2005
Confirmation No.: 4686

REMARKS

In view of the amendments set forth above and the remarks that follow, reconsideration and allowance of the subject claims is respectfully requested.

Claim 1 has been amended to incorporate the requirements of claim 5 as to the amount of anti-dandruff agent. Additionally claim 1 has been amended to further specify the amount of conjugated linoleic acid (CLA) as from 0.01 to 5 wt%. Applicants refer to the first full paragraph appearing at page 9 of the specification wherein it is disclosed that the preferred amount of CLA is from 0.001 to 5 wt%, more preferably from 0.001 to 2 wt% and most preferably from 0.01 to 1% by weight of the total composition. Applicants submit that a range that incorporates the most preferred minimum of 0.01 wt% CLA and a maximum defined by the 5 wt% level of the broadest preferred range is supported by the specification. Similar limitations have been incorporated into claim 7. See, for example, the specification at page 29, last paragraph to 30, line 3:

The system of the invention for treating dandruff (which can also be termed a kit of parts) comprises a first component comprising an anti-dandruff agent; and a second component comprising conjugated linoleic acid (CLA). The first component and the second component are both suitable for, and are preferably adapted for, topical application to the scalp... The first component and the second component are applied to the scalp in the desired order depending upon their respective formulations (which may be formulated as described above in connection with the compositions of the invention)...

Claims 5 and 6 have been cancelled without prejudice. Claim 13 has been amended to write out the abbreviation CLA as "conjugated linoleic acid".

Attorney Docket No.: J3692(C)
Serial No.: 10/531,155
Filed: September 26, 2005
Confirmation No.: 4686

Pursuant to the Office Action of September 21, 2007, the pending claims stand rejected under Hoppe et al. (US2003/0180277) in view of Hersh (US 6011067).

Hoppe et al. discloses the use of bioquinones to prolong the analgenic phase of hair growth and to treat dandruff. There is nothing in the citation that discloses or suggests that CLA (described therein as improving the energy metabolism in the hair root) would be effective in treating scalp itch. Hersh et al. discloses anti-dandruff compositions that contain zinc PTO. There is nothing in the citation that discloses or suggests the use of CLA in such compositions. The outstanding Office Action relies WO00/37040 to connect Hoppe et al. and Hersh et al.

WO00/37040 discloses that skin care compositions enriched in cis-9, trans-11 linoleic acid or derivatives thereof are useful for the treatment of normal skin conditions due to ageing or chronoaging, such as wrinkles lines, sagging, hyperpigmentation and age spots, and/or treatment of sensitive, dry, rough, flaky red, itchy and irritated skin, WO 00/37040 also discloses that CLA helps prevent or reduce wrinkles and increases flexibility, firmness, smoothness, suppleness and elasticity of the skin.

As previously noted, the data provided in the subject application shows that, in the context of itching associated with dandruff, when used in conjunction with a non-anti-dandruff (NAD) shampoo, a CLA-containing lotion was actually found to increase, not reduce, itching. More particularly, dandruff sufferers in Group 1 of the test panel (panellists who used a NAD shampoo and a CLA-containing lotion) reported more severe itching than the panellists who used the NAD shampoo and a CLA-free lotion (Group 2). Users of the antidandruff (AD) shampoo in conjunction

Attorney Docket No.: J3692(C)
Serial No.: 10/531,155
Filed: September 26, 2005
Confirmation No.: 4686

with the CLA-free lotion (Group 4) reported less severe itching compared to panellists who used the NAD shampoo used with the CLA-free lotion (Group 2), which would be expected, and verifies the NAD/CLA-free lotion control. However, given the results of the Group 1 panellists (who exhibited an increase in itching seemingly related to the use of CLA), it is surprising that a CLA-containing lotion would enhance, rather than impair, itch reduction when used with an AD shampoo, and that the panellists who used the AD shampoo with the CLA-containing lotion (Group 3) would experience the least amount of itching of the various test groups.

It is noted that the subject data was derived using a total of 240 test subjects who were divided into four groups of 60 panellists per group. Regarding the significance of the reported data, page 36 the application reports that analysis of itch scores is carried out using analysis of variance to test for main effects and interactions of the NAD and AD shampoo and CLA-containing lotion and that the individual comparisons are tested for significant differences at the 5% level; in these type of tests, the generally accepted probability for demonstrating statistical difference. Thus, notwithstanding that the ascertained differences in itching are generally somewhere between mild and moderate ratings, what are reported are statistically real and significant differences that show an unexpected improvement provided by the claimed combination of CLA and antidandruff agent on dandruff related itch, in testing carried out on a relatively large group of test subjects.

Accordingly, it is respectfully submitted that the combination of CLA +AD agent provides a surprising and synergistic enhancement in itch reduction that would not be predicted based on the performance of either component individually. While the Office Action suggests that the teaching of the references should outweigh the subject data, it is respectfully submitted that the observed performance of CLA is of

Attorney Docket No.: J3692(C)
Serial No.: 10/531,155
Filed: September 26, 2005
Confirmation No.: 4686

greater relevance than disclosures made in the context of applications other than the treatment of dandruff.

Applicants incorporate herein the additional arguments previously made with respect to Hoppe et al. and Herb et al. and request reconsideration and allowance of the claims, as hereby amended.

If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,



Karen E. Klumas
Registration No. 31,070
Attorney for Applicant(s)

KEK/sa
(201) 894-2332